

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of the effect of selenium supplementation on sonographic findings of salivary glands and inflammatory factors and oxidative stress in patients with thyroid cancer treated with radioactive iodine

Protocol summary

Study aim

Determining the effect of selenium supplementation on sonographic findings of salivary glands and inflammatory factors and oxidative stress in patients with thyroid cancer treated with radioactive iodine

Design

Clinical trial, randomized, double-blind, randomized control group of 60 patients. Randomization is done using a valid website and 4-block method.

Settings and conduct

This clinical trial will be performed in the special clinic of Al-Zahra Hospital. Selenium and placebo are prescribed to the patient in exactly the same packaging. Patients and researchers will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Age 20 to 65 years Diagnosis of thyroid cancer by imaging, such as ultrasound, computed tomography, magnetic resonance imaging, and positron tomography (PET) scan

Intervention groups

Intervention group: Patients who receive a selenium capsule containing 200 micrograms of selenium per day for 10 days (3 days before treatment with radioactive iodine to 6 days after treatment with radioactive iodine). Control group: Patients receiving a placebo capsule containing 200 micrograms of maltodextrin per day for 10 days (3 days before radioactive iodine treatment up to 6 days after radioactive iodine treatment)

Main outcome variables

Before and after studying the clinical status of salivary glands, blood CRP, oxidative stress indices including total antioxidant capacity (TAC) and total oxidative capacity (TOS) and the sense of taste and secretion of salivary glands are evaluated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201129049534N6**

Registration date: **2021-09-16, 1400/06/25**

Registration timing: **prospective**

Last update: **2021-09-16, 1400/06/25**

Update count: **0**

Registration date

2021-09-16, 1400/06/25

Registrant information

Name

Mohammad bagherniya

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3183

Email address

bagherniya@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-06, 1400/07/14

Expected recruitment end date

2022-10-06, 1401/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of selenium supplementation on sonographic findings of salivary glands and inflammatory factors and oxidative stress in patients with thyroid cancer treated with radioactive iodine

Public title

Evaluation of the effect of selenium on patients with thyroid cancer treated with radioactive iodine

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages 20 to 65 Diagnosis of thyroid cancer by imaging, such as ultrasound, computed tomography, magnetic resonance imaging, and positron tomography (PET) scan

Exclusion criteria:

History of sialadenitis (inflammation of the salivary glands) Sjogren's history of collagen vascular disease involving the salivary glands. History of any salivary gland surgery Follow a special diet in the last 3 months Pregnancy and lactation Patient dissatisfaction to participate in the study Taking dietary supplements in the last 3 months Suffering from certain diseases such as diseases caused by congenital diseases, immune system defects, etc.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done individually. Entry of each patient into the intervention or control group is done randomly with the help of 4 blocking. This is done using a reputable random number generation website. (Random number generation website: <https://www.sealedenvelope.com/simple-randomiser/v1/li-sts>)

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be double blinded so that the researcher and the subjects will not know which group they belong to. For blinding, selenium and placebo capsules are prepared in the same shape, color and size. These capsules are coded by someone other than the researchers (A and B) and then the capsules are given to patients. Until the end of the study and after analyzing the data, researchers will not know about the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

School of Nutrition and Food Sciences, Isfahan University of Medical Sciences, Hezar-jerib Avenue

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-09-05, 1400/06/14

Ethics committee reference number

IR.MUI.MED.REC.1400.420

Health conditions studied**1****Description of health condition studied**

Thyroid cancer

ICD-10 code

D44.0

ICD-10 code description

Neoplasm of uncertain behavior of thyroid gland

Primary outcomes**1****Description**

Clinical status of salivary glands

Timepoint

At baseline and end of the study

Method of measurement

Ultrasound of major salivary glands (including examination of echogenicity, size, margin and contour)

2**Description**

C reactive Protein (CRP)

Timepoint

At baseline and end of the study

Method of measurement

ELISA test

3

Description

Total oxidative stress

Timepoint

At baseline and end of the study

Method of measurement

Commercial diagnostic kit

4

Description

Total antioxidant capacity

Timepoint

At baseline and end of the study

Method of measurement

Commercial diagnostic kit

5

Description

Sense of taste

Timepoint

At baseline and end of the study

Method of measurement

Questionnaire designed by the researcher

6

Description

The rate of salivary gland secretion

Timepoint

At baseline and end of the study

Method of measurement

Questionnaire designed by the researcher

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receiving a selenium capsule containing 200 micrograms of selenium per day for 10 days (3 days before treatment with radioactive iodine to 6 days after treatment with radioactive iodine)

Category

Treatment - Drugs

2

Description

Control group: Patients receiving a placebo capsule containing 200 micrograms of maltodextrin per day for 10 days (3 days before radioactive iodine treatment to 6 days after radioactive iodine treatment)

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Al-Zahra Hospital

Full name of responsible person

Sepide Amini Semiromi

Street address

Soffe Blvd

City

Isfahan

Province

Isfahan

Postal code

81746 75731

Phone

+98 31 3620 2020

Email

amini.spide@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Hagh Joy Javanmard

Street address

Hezar-jerib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 21 8145 5618

Email

ethics@behdasht.gov.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Bagherniya

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Hezar-jerib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3972 3138

Email

bagherniya@nutr.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Bijan Iraj

Position

Endocrinology and metabolism

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinologist

Street address

Hezar-jerib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3171

Email

bijaniraj@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Bagherniya

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Hezar-jerib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3972 3138

Email

bagherniya@nutr.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study information will be published after the individuals are unidentified and after the project is completed.

When the data will become available and for how long

Access period starts six months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For further analysis

From where data/document is obtainable

Dr. Mohammad Baghernia bagherniya@nutr.mui.ac.ir

What processes are involved for a request to access data/document

After reviewing the request and making it fully clear about the purposes of using the data, the data will be provided

Comments